

REMARKS

By this amendment, claims 1 and 10 have been amended for clarification. Claims 1-10 remain in the application. Support for the amendments to the claims can be found in the specification and drawings. No new matter has been added. Reconsideration, withdrawal of the final action, and allowance of the application, as amended, is respectfully requested.

Rejection under 35 U.S.C. §103

Claim 1:

Claim 1 recites a device for navigating an instrument in a body volume that is subject to a spontaneous movement that can be described by a movement parameter (E), comprising:

- a) a locating device for measuring a location (r) of the instrument;
- b) a sensor device for measuring the movement parameter (E); and
- c) a data processing device coupled to the locating device and the sensor device, wherein the data processing device comprises a movement model that describes, with respect to a reference phase (E_0) of the movement parameter, a spontaneous movement field or vectorial displacement (Δ) to which interpolation nodes of the body volume are subject in the various phases of the movement parameter (E), wherein with (i) the aid of the movement model, (ii) a current measured location (r) and (iii) an associated current movement parameter, the data processing device calculates an estimated movement-compensated location ($r + \Delta$), corresponding to the current measured location (r) plus the vectorial displacement (Δ), of the instrument that the instrument would have in the reference phase (E_0) of the spontaneous movement field.

Support for the amendments to claim 1 (as well as for amendments to claim 10), can be found in the specification at least on page 6, lines 1-4 and 25-27, as originally filed.

The device of claim 1 makes it possible to track the movement of an instrument in the body volume with respect to a certain, specified reference phase of the spontaneous movement of the body volume. The effect of the spontaneous movement of the body volume on the instrument is compensated for so that *only* the relative movement, important for navigation, is left over between instrument and body volume. The device requires *only* the movement model stored in the data processing device and also the locating device and the sensor device. In addition, the movement-compensated position ... is situated ... on the vessel map ... as a rule, within the vessel system so that *confusing deviations* between the instrument location shown and the layout of the vessels do not arise as a result of the heartbeat. (See the specification, page 6, lines 13-16).

Claims 1 and 7-10 were rejected under 35 U.S.C. §103(a) as being unpatentable over **Rasche** (US 6,473,635; herein referred to as **Rasche**). With respect to claim 1, Applicant traverses this rejection on the grounds that the reference is defective in establishing a prima facie case of obviousness.

As the PTO recognizes in MPEP § 2142:

... The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness ...

It is submitted that, in the present case, the examiner has not factually supported a prima facie case of obviousness for the following reasons.

1. The Reference Do Not Teach the Claimed Subject Matter

The **Rasche** reference cannot be applied to reject claim 1 under 35 U.S.C. § 103 which provides that:

A patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains ... (Emphasis added)

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. However, since the **Rasche** reference neither teaches or suggests "a *movement model* that describes, with respect to a reference phase (E_0) of the movement parameter, a *spontaneous movement field* or *vectorial displacement* (Δ) to which *interpolation nodes* of the body volume are subject in the various phases of the movement parameter (E), wherein with (i) the aid of the movement model, (ii) a current measured location (r) and (iii) an associated current movement parameter, the *data processing device* calculates an estimated *movement-compensated location* ($r + \Delta$), corresponding to the current measured location (r) plus the vectorial displacement (Δ), of the instrument that the instrument *would have* in the *reference phase* (E_0) of the *spontaneous movement field*" (emphasis added) as is claimed in claim 1, it is impossible to render the subject matter of claim 1 as a whole obvious, and the explicit terms of the statute cannot be met.

In contrast, the **Rasche** reference teaches a method and device for determining the position of a medical instrument in which eigenmotion of the heart is taken into account for determining the position of the catheter relative to the heart. (See Rasche at col. 4, lines 64-66). The **Rasche** reference further teaches "3D-image data sets are associated not only with the individual phases of motion of the electrocardiogram but also with individual phases of motion of the respiratory motion, so that a five-dimensional set (3D image data set + cardiac motion phase + respiratory motion phase) is then stored in the image data base. (See Rasche at col. 7, lines 28-33). However, the **Rasche** reference neither teaches nor suggests "a *movement model* that describes, with respect to a reference phase (E_0) of the movement parameter, a *spontaneous movement field* or *vectorial displacement* (Δ) to which *interpolation nodes* of the body

volume are subject in the various phases of the movement parameter (E), wherein with (i) the aid of the movement model, (ii) a current measured location (r) and (iii) an associated current movement parameter, the *data processing device* calculates an estimated *movement-compensated location* ($r + \Delta$), corresponding to the current measured location (r) plus the vectorial displacement (Δ), of the instrument that the instrument *would have* in the *reference phase* (E_0) of the *spontaneous movement field*" as is specifically claimed in claim 1.

Thus, for this reason, the examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection under 35 U.S.C. §103 should be withdrawn.

2. The recognition of a problem, or of the source of the problem, is not obvious even though the solution to the problem may be obvious

In the present case, it is apparent from a reading of the **Rasche** reference that it did not recognize the problem of tracking the movement of an instrument in the body volume with respect to a certain, specific reference phase of the spontaneous movement of the body volume, wherein the effect of the spontaneous movement of the body volume is compensated for in this connection so that only the relative movement, important for navigation, is left over between the instrument and the body volume. In addition, the **Rasche** reference further did not recognize calculation of a spontaneous movement model based on an observed movement of interpolation nodes and an interpolation of the measured movement of the interpolation nodes, nor that a precision of the movement model can be adjusted as desired by means of the density of a network of interpolation nodes. Thus, this is a classic example of a solution to a problem being obvious only after recognition of the problem by the applicant and is part of the "subject matter as a whole" language of 35 USC § 103 which should always be considered in determining the obviousness of an invention under this statute.

Thus, for this reason, the examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection under 35 U.S.C. §103 should be withdrawn.

3. The Combination of References is Improper

Assuming, arguendo, that none of the above arguments for non-obviousness apply (which is clearly not the case based on the above), there is still another compelling reason why the **Rasche** reference cannot be applied to reject claim 1 under 35 U.S.C. §103.

§ 2142 of the MPEP also provides:

...the examiner must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made The examiner must put aside knowledge of the applicant's disclosure, refrain from using hindsight, and consider the subject matter claimed 'as a whole'.

Here, **Rasche** neither teaches, or even suggests, the desirability of the combination since **Rasche** does not teach the specific "*movement model* that describes, with respect to a reference phase (E_0) of the movement parameter, a *spontaneous movement field* or *vectorial displacement* (Δ) to which *interpolation nodes* of the body volume are subject in the various phases of the movement parameter (E), wherein with (i) the aid of the movement model, (ii) a current measured location (r) and (iii) an associated current movement parameter, the *data processing device* calculates an estimated *movement-compensated location* ($r + \Delta$), corresponding to the current measured location (r) plus the vectorial displacement (Δ), of the instrument that the instrument *would have* in the *reference phase* (E_0) of the *spontaneous movement field*" (emphasis added) as specified above and as claimed in claim 1.

Thus, it is clear that neither patent provides any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. §103 rejection.

In this context, the MPEP further provides at § 2143.01:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.

In the above context, the courts have repeatedly held that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination.

In the present case it is clear that the examiner's combination arises solely from hindsight based on the invention without any showing, suggestion, incentive or motivation in either reference for the combination as applied to claim 1. Therefore, for this reason, the examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection under 35 U.S.C. §103 should be withdrawn.

Accordingly, claim 1 is allowable and an early formal notice thereof is requested. Claims 7-9 depend from and further limit, in a patentable sense, independent claim 1 and therefore is allowable as well. Accordingly, the 35 U.S.C. § 103(a) rejection thereof has now been overcome.

By this amendment, claim 10 has been amended in a similar manner as with respect to the amendments to claim 1. Accordingly, claim 10 is believed allowable for at least the same reasons as those presented herein above with respect to overcoming the rejection of claim 1. Withdrawal of the rejection is respectfully requested.

Claims 2-6 were rejected under 35 U.S.C. §103(a) as being unpatentable over **Rasche** (US 6,473,635) in view of **Branham et al.** (U.S. 5,687,737; herein referred to as **Branham**). Applicant respectfully traverses this rejection for at least the following reason. Claims 2-6 depend from and further limit independent claim 1, in a patentable

sense, and therefore are allowable as well. The 35 U.S.C. §103(a) rejection thereof has now been overcome. Withdrawal of the rejection is requested.

Conclusion

Except as indicated herein, the claims were not amended in order to address issues of patentability and Applicants respectfully reserve all rights they may have under the Doctrine of Equivalents. Applicants furthermore reserve their right to reintroduce subject matter deleted herein at a later time during the prosecution of this application or a continuation application.

It is clear from all of the foregoing that independent claims 1 and 10 are in condition for allowance. Claims 2-9 depend from and further limit independent claim 1, and therefore are allowable as well.

The amendments herein are fully supported by the original specification and drawings; therefore, no new matter is introduced. An early formal notice of allowance of claims 1-10 is requested.

Respectfully submitted,

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